

### **Remarks**

This communication responds to the Office Action mailed November 24, 2009 for the application captioned above. By this amendment, claim 1 is amended and claims 7 and 8 are cancelled, without prejudice or disclaimer of the subject matter therein. No new matter has been added as a result of this amendment. The following remarks are respectfully submitted.

### **Election/Restrictions**

The Examiner has determined that newly submitted claims 30-33 are directed to an invention distinct from the invention originally claimed, and has withdrawn claims 30-33 from consideration as being directed toward a non-elected invention. Accordingly, Applicant, by the present amendment, designates claims 30-33 as being withdrawn.

### **§103 Rejection**

Claims 1, 3, 4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Putz (US 4,903,702). Applicant has cancelled claims 7 and 8, without prejudice or disclaimer of the subject matter therein, rendering the rejection of claims 7 and 8 moot. Applicant respectfully traverses the rejection of claims 1, 3, 4 and 6 and 9, based upon the remarks presented below.

Applicant has amended independent claim 1 in order to further specify that portion of the paddle which is free from electrodes and extends proximally from the electrode array to the proximal end of the paddle, and to further specify the location of the orientation marker. Support for amended claim 1 may be found in the application as originally filed, for example, with reference to the pre-grant publication thereof (US 2004/0260310), in paragraphs [0007]-[0009], [0060], [0065] and [0066] and in Figure 6, a copy of which is shown below. Applicant respectfully asserts that Putz neither teaches nor suggests all the limitations of amended claim 1, and respectfully presents the following chart in which selected limitations of claim 1 are placed side-by-side with excerpts from the disclosure of Putz to highlight the differences therebetween.

**Claim 1 (example illustrated by Fig. 6)**

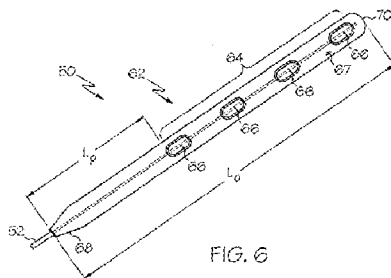


FIG. 6

**Disclosure of Putz**

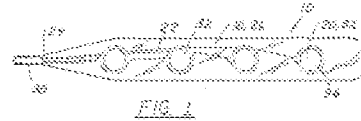


FIG. 1

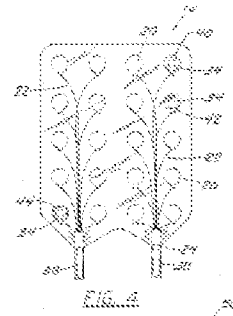
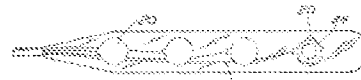


FIG. 3

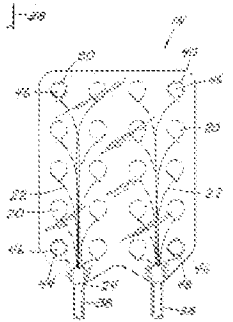


FIG. 4

"...an electrode array...the electrode array being displaced longitudinally from the proximal end (68) of the paddle such that a portion of the paddle that is free of electrodes extends proximally from the electrode array to the proximal end of the paddle, over a length ( $L_p$ ) that is sufficient to allow the portion that is free of electrodes to extend through connective tissue so that the proximal end of the paddle is positioned outside an epidural space when the entire electrode array is positioned within the epidural space alongside the spinal cord, the length being at least 40 mm"

Column 5, lines 40-51:

While the thickness of contacts 20 make them difficult to locate by x-ray, the inclusion of radiopaque dielectric marker ring 34 against distal contact 36 and radiopaque dielectric sheathing 38 extending from proximal edge 24 allow, or greatly facilitate, determination of intracranial positions of contacts 20 by x-ray at desirable x-ray settings. Subdural strip electrode 10, during its use, is located between the dura and the gray matter. X-ray viewing of the positions of radiopaque dielectric ring 34 and radiopaque sheathing 38 provides precise knowledge of the positions of each of contacts 20 along strip 10.

<p>“...an orientation marker (67) being displaced from the longitudinal center line, on one side thereof, from every electrode (66) of the electrode array (64), and longitudinally from the portion of the paddle that is free of electrodes, such that the orientation marker is positioned in the epidural space, with the entire electrode array, when the proximal end of the paddle is positioned outside the epidural space, the single orientation marker including radio-opaque material such that, when the orientation marker is viewed under fluoroscopy, as being on a particular side of the longitudinal center line, the direction in which the first major surface of the paddle faces can be determined in order to know if the first major surface of the paddle, through which each electrode of the electrode array is exposed, faces toward the spinal cord for stimulation thereof, via the electrode array.”</p>	<p>Column 5, lines 40-46:</p> <p>While the thinness of contacts 20 make them difficult 40 to locate by x-ray, the inclusion of radiopaque dielectric marker ring 34 against distal contact 36 and radiopaque dielectric sheathing 38 extending from proximal edge 24 allow, or greatly facilitate, determination of intracranial positions of contacts 20 by x-ray at desirable x-ray set- 45 tings. Subdural strip electrode 10, during its use, is lo-</p> <p>Column 6, lines 1- 23 and 31-40:</p> <p>While subdural strip electrode 10 has a single row of contacts 20, grid electrodes 12 and 14 of FIGS. 4 and 5 have arrays of contacts 20 which include four rows with five contacts each. The construction of grid elec- 3 trodes 12 and 14 is similar to that of strip electrode 10. That is, each has a similar flexible dielectric strip or base 18 which is formed from two layers, and the contacts and leads are similar to those of strip electrode 10. Ex- tending from proximal edge 24 of the flexible dielectric 10 material 18 of grid electrodes 12 and 14 are two dielec- tric sheathings 38. Such sheathings are radiopaque di- electric sheathings as previously described.</p> <p>Grid electrode 12, as shown in FIG. 4, has three radiopaque dielectric ring markers 34 arranged in a 15 particular way to aid in determination of the position of each of the contacts 20 of such device. In FIG. 4, radi- opaque dielectric rings 34 are located adjacent to a first contact 40 which is at the upper right hand corner as seen in FIG. 4, a second contact 42 which is immedi- 20 ately adjacent to first contact 40, and a last contact 44 which is at a position diagonally opposite the position of first contact 40.</p> <p>Grid electrode 14 of FIG. 5 differs from grid elec- trode 12 of FIG. 4 in several respects. First, it has four radiopaque markers rather than three. Second, such radiopaque markers are disks 46, rather than rings. And 35 third, the marker placement is somewhat different. Ra- diopaque dielectric disks 46 are located adjacent to first contact 40 and last contact 44, each positioned as in the device of FIG. 4, and adjacent to contacts 48 and 50, which are in the lower right-hand and upper left-hand 40 corners, as shown in FIG. 5.</p>
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In response to Applicant's prior remarks, which were filed in the response to the Office Action dated May 14, 2009, the Examiner emphasizes that "Putz teaches the employment of orientation markers to distinguish the location of electrodes in the electrode array", a point which Applicant does not dispute. The Examiner further asserts that moving or relocating the radiopaque markers of Putz away from the electrodes would still enable Putz to determine the

position of the electrodes so that such a modification of Putz would render the invention of Putz satisfactory for its intended purpose. Applicant respectfully disagrees based upon the express teaching of Putz, for example, in the Abstract of Putz, in the detailed description of Putz, as referenced above, and in that portion of the disclosure that identifies an object of the invention as being to overcome the problems and shortcomings of the prior art, which Putz defines in column 2, lines 27-40 (with particular reference to lines 32-40):

It is, therefore, desirable to make post-insertion checks on the precise location of the array of contacts of intracranial brain-contact devices, using x-rays.  
30 However, such location checks have been difficult at best primarily because of the nature of the electrical contacts. This is particularly the case with subdural strip and grid electrodes, in which the metal contacts, particularly the disks of subdural strip and grid elec-  
35 trodes, are themselves so thin and delicate that they cannot be seen or seen readily at desired x-ray powers.

There is a significant need for an improved electrical brain-contact device allowing a high degree of post-insertion confidence with respect to the intracranial  
40 positions of the electrical contacts.

#### OBJECTS OF THE INVENTION

It is an object of this invention to provide an improved electrical brain-contact device overcoming the  
45 problems and shortcomings of the prior art mentioned above.

In further response to Applicant's prior remarks, with respect to the limitation concerning the length of the electrode free portion defined by claim 1, the Examiner maintains that "Putz does not disclose the exact length of the electrode free portion and it would be obvious to modify the length of the electrode free portion in order to provide predictable results of ensuring proper stimulation or sensing to locations." In response, Applicant has amended claim 1 in order to further specify that the length of the portion of the paddle that is free of electrodes is sufficient to allow the portion to extend through connective tissue such that the proximal end of the paddle is positioned outside an epidural space when the entire electrode array is positioned within the epidural space alongside the spinal cord. Since the disclosure of Putz is directed toward an improved electrical brain-contact device, which includes either a subdural strip electrode 10, or grid electrodes 12, 14, Putz discloses configurations of the electrodes 10, 12, 14 that are suitable

for intracranial implantation between the dura and the gray-matter, and in no way contemplates placement of the electrodes 10, 12, 14 for spinal cord stimulation. Thus, Applicant respectfully asserts that one skilled in the art, when referencing the disclosure of Putz, without hindsight benefit of the present disclosure, would not be motivated to modify any of the electrodes 10, 12, 14 of Putz to include an electrode-free portion having a length, as defined by claim 1.

Furthermore, as Applicant has previously pointed out, Putz discloses that a determination of intracranial positions of contacts 20, by x-ray, is greatly facilitated by radiopaque dielectric marker ring 34 against distal contact 36 *and* radiopaque dielectric sheathing 38, which extends from the proximal edge 24 of the strip 18. Thus, Putz teaches away from any significant displacement between a proximal edge 24 of electrodes 10, 12, 14 and the most proximal electrode contact 20, let alone one that would cause the proximal edge 24 to be positioned outside an epidural space, since the precise knowledge described by Putz in lines 46-51 of column 5, would not be provided if the proximal edge 24 and the most proximal contact 20 were significantly displaced from one another.

In light of the arguments presented above, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1, 3, 4, 6, 8 and 9.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested. Applicant believes no fee is due to enter the present Amendment. The Commissioner is hereby authorized to charge any additional filing fees required to Deposit Account No. 061910. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

Dated: December 16, 2009

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